



# SAFETY DATA SHEET

Revision date 16-Nov-2020

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Pfizer-BioNTech COVID-19 Vaccine

**Product Code(s)** PF00092

**Synonyms** PF-07302048 containing PF-07305885 (BNT162b2); CorVAC Containing PF-07305885 (BNT162b2) ; CoVVAC Containing PF-07305885 (BNT162b2); COVID Vaccine Containing PF-07305885 (BNT162b2); COVID-19 Vaccine Containing PF-07305885 (BNT162b2)

**Trade Name:** Not applicable

**Compound Number** PF-07302048

**Item Code** H000022941: H000023057

**Chemical Family:** Lipid Nanoparticles containing PF-07305885 (BNT162b2) and Lipids

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

**E-mail address** pfizer-MSDS@pfizer.com

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

Not classified as hazardous

### 2.2. Label elements

**Signal word** Not classified

**Hazard statements** Not classified in accordance with international standards for workplace safety.

### 2.3. Other hazards

**Other hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	*	Not Listed	
Sucrose	200-334-9	57-50-1	< 10	Not Listed	
SODIUM CHLORIDE	231-598-3	7647-14-5	< 10	Not Listed	
ALC-0315	Not Listed	NOT ASSIGNED	< 2	Not Listed	
Potassium phosphate	231-913-4	7778-77-0	< 1	Not Listed	
POTASSIUM CHLORIDE	231-211-8	7447-40-7	< 1	Not Listed	
PF-07305885	Not Listed	NOT ASSIGNED	< 1	Not Listed	
PF-07302048	Not Listed	NOT ASSIGNED	< 1	Not Listed	
PEGA / ALC-0159	Not Listed	NOT ASSIGNED	< 1	Not Listed	
Disodium phosphate dihydrate	Not Listed	10028-24-7	< 1	Not Listed	
Cholesterol	200-353-2	57-88-5	< 1	Not Listed	
1,2-Distearoyl-sn-glycero-3-phosphocholine	212-440-2	816-94-4	< 1	Not Listed	

**Full text of H- and EUH-phrases: see section 16**

**Additional information** \* Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and** No data available

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## effects

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on safe handling**

Restrict access to work area. No open handling permitted. Minimize generating airborne mists and vapors. If solvent based liquid, ground and bond all bulk transfer equipment. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere

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should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store at < -70 °C in properly labeled containers. Keep away from heat, sparks, and flames.

## 7.3. Specific end use(s)

**Specific use(s)** Vaccine.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

Refer to available public information for specific member state Occupational Exposure Limits.

#### **Sucrose**

ACGIH TLV	10 mg/m <sup>3</sup>
Bulgaria	10.0 mg/m <sup>3</sup>
Estonia	10 mg/m <sup>3</sup>
France	10 mg/m <sup>3</sup>
Ireland	10 mg/m <sup>3</sup>
	STEL: 20 mg/m <sup>3</sup>
Latvia	5 mg/m <sup>3</sup>
Spain	10 mg/m <sup>3</sup>
OSHA PEL	15 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
	(vacated) TWA: 15 mg/m <sup>3</sup> total dust
	(vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction
United Kingdom	TWA: 10 mg/m <sup>3</sup>
	STEL: 20 mg/m <sup>3</sup>

#### **SODIUM CHLORIDE**

Latvia	5 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>

#### **Potassium phosphate**

Russia	MAC: 10 mg/m <sup>3</sup>
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#### **POTASSIUM CHLORIDE**

Bulgaria	5.0 mg/m <sup>3</sup>
Latvia	5 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>

#### **Pfizer OEB Statement:**

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

#### **SODIUM CHLORIDE**

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### **POTASSIUM CHLORIDE**

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### **PF-07305885**

Pfizer Occupational Exposure Band (OEB): B-OEB Default (control exposure to the range of 10 µg/day to <100 µg/day)

#### **PF-07302048**

Pfizer Occupational Exposure Band (OEB): B-OEB 5 (control exposure to <10 µg/day)

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Band (OEB):

## **8.2. Exposure controls**

<b>Engineering controls</b>	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. It is recommended that all large scale operations should be fully enclosed. Air recirculation is not recommended.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Eye/face protection</b>	Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
<b>Hand protection</b>	Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
<b>Skin and body protection</b>	Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). Wear impervious protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
<b>Respiratory protection</b>	Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## **Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

### **9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	Liquid
<b>Color</b>	milky white
<b>Molecular formula (MF):</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Odor</b>	No data available.
<b>Odor threshold</b>	No data available
<b>Property</b>	<b>Values</b>
<b>pH</b>	7.4
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	No data available
<b>Flash point</b>	No data available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available

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Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

## 9.2. Other information

Liquid Density	No data available
Bulk density	No data available

## **Section 10: STABILITY AND REACTIVITY**

### 10.1. Reactivity

Reactivity No data available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

### Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

### 10.4. Conditions to avoid

Conditions to avoid Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

### 10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### 11.1. Information on toxicological effects

**General Information:** Toxicological properties have not been thoroughly investigated. The following information is available for the individual ingredients.

**Known Clinical Effects:** Based on clinical trials in humans, possible adverse effects following intravenous exposure to this compound may include: muscle pain, abnormal redness of skin (erythema), fever, and sleep disturbances.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Sucrose

Rat Oral LD 50 29,700 mg/kg

#### SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3 g/kg

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Mouse Oral LD 50 4 g/kg  
Rabbit Dermal LD 50 > 10 g/kg

## **POTASSIUM CHLORIDE**

Rat Oral LD50 2600 mg/kg

## **Potassium phosphate**

Rat Oral LD50 3200 mg/kg

Rabbit Dermal LC50 > 4640 mg/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Sucrose	= 29700 mg/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3 g/kg ( Rat )	-	> 42 g/m <sup>3</sup> ( Rat ) 1 h
Potassium phosphate	= 3200 mg/kg ( Rat )	-	-
POTASSIUM CHLORIDE	= 2600 mg/kg ( Rat )	-	-

## **Irritation / Sensitization: (Study Type, Species, Severity)**

### **SODIUM CHLORIDE**

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

### **POTASSIUM CHLORIDE**

Eye Irritation Rabbit Mild

## **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

### **PF-07302048**

4 Week(s) Rat Intramuscular \* 10 µg LOAEL Skin, Blood forming organs, Blood, Skeletal muscle, Lymphoid tissue, Spleen

**Repeated Dose Toxicity Comments: PF-07302048:** \* Doses were administered once a week.

## **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Potassium phosphate**

Reproductive & Fertility Rat No route specified 282 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

Reproductive & Fertility Mouse No route specified 320 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

## **Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

### **Potassium phosphate**

Bacterial Mutagenicity (Ames) *Salmonella* Negative

### **Carcinogenicity**

See below

### **Cholesterol**

IARC

Group 3 (Not Classifiable)

## **Section 12: ECOLOGICAL INFORMATION**

### **Environmental Overview:**

Environmental properties have not been investigated. Releases to the environment should be avoided.

### **12.1. Toxicity**

#### **Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

##### **POTASSIUM CHLORIDE**

*Gambusia affinis* (Mosquitofish) LC50 96 hours 920 mg/l

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*Lepomis macrochirus* (Bluegill Sunfish) LC50 96 hours 2010 mg/L  
*Daphnia Magna* (Water Flea) EC50 48 hours 825 mg/l  
*Scenedesmus subspicatus* (Green Alga) EC50 72 Hours 2500 mg/L

## 12.2. Persistence and degradability

**Persistence and degradability** No information available.

## 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

Chemical Name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Potassium phosphate	The substance is not PBT / vPvB PBT assessment does not apply
POTASSIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Cholesterol	The substance is not PBT / vPvB

## 12.6. Other adverse effects

**Other adverse effects** No information available.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## **Section 14: TRANSPORT INFORMATION**

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.



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## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

Sucrose

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-334-9
<b>AICS</b>	Present

SODIUM CHLORIDE

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present

ALC-0315

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

Potassium phosphate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-913-4
<b>AICS</b>	Present

POTASSIUM CHLORIDE

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-211-8
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

PF-07305885

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

PF-07302048

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

PEGA / ALC-0159

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

Disodium phosphate dihydrate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and</b>	Schedule 5

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## Poisons (SUSMP)

Cholesterol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-353-2
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

1,2-Distearoyl-sn-glycero-3-phosphocholine

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	212-440-2

## 15.2. Chemical safety assessment

Chemical Safety Report No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date** 16-Nov-2020

**Prepared By** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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